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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,710	09/26/2003	Joseph William Epstein	AM100079 D1	1134
25291	7590	05/07/2004	EXAMINER	
WYETH PATENT LAW GROUP FIVE GIRALDA FARMS MADISON, NJ 07940			SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 05/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,710

Applicant(s)

EPSTEIN ET AL.

Examiner

Robert Shiao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on application filed 09/26, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0504.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. This application claims benefit of the provisional application: 60314585 with a filing date 08/24/2001.
2. Cancellation of claims 1-10 and 20-25 in Paper No.0903, dated September 26, 2003, is acknowledged. Claims 11- 19 are pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 11-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter "ras-associated diseases", which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, see claim 11, line 1.
5. Claims 11-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of use treating breast cancer of "ras-associated diseases", does not reasonably provide enablement for methods of use treating diabetes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention

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commensurate in scope with these claims, see claim 11, line 1. Incorporation of the named diseases into the claims would obviate the rejection, see page 6, lines 20-31.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claims are drawn to methods of use treating ras-associated diseases without limitation.

2) State of the prior art.

The reference Shimizu-Nishikawa et al. publication, see CAS: 134:364384, does not indicate which compounds of instant compounds may be useful in the claimed

invention. Shimizu-Nishikawa et al. publication is pertaining to Identification and characterization of newt rad (ras associated with diabetes).

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The claimed methods of use treating ras-associated diseases without limitation, encompasses a vast number of methods. Applicant's specification does not enable the public to prepare such a numerous methods of use of formula I by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The claimed methods of use treating ras-associated diseases without limitation, remains highly unpredictable, see claim 11, line 1. Different types of methods of use for treating "ras-associated diseases", require various experimental procedures and without guidance that is applicable to all possible methods of use treating "ras-associated diseases" without limitation, there would be little predictability in the scope of claimed methods.

5) Amount of direction and guidance provided by the inventor.

The genus of the claimed methods of use treating ras-associated diseases without limitation, encompasses a vast number of methods. Applicant's limited guidance does not enable the public to prepare such a numerous amount of "methods of use treating ras-associated diseases without limitation" in the specification. There is no enablement for methods of use treating ras-associated diseases, wherein diseases representing diabetes, etc., many of which are neither enabled nor supported in the specification.

6) Existence of working examples.

The genus of claimed "methods of use treating ras-associated diseases without limitation", encompasses a vast number of methods. Applicant's limited working examples do not enable the public to prepare such a "methods of use treating ras-associated diseases without limitation" in the specification. Applicants claim "methods of use treating ras-associated diseases without limitation", however, the specification provides only limited examples of the instant compounds.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "methods of use treating ras-associated diseases without limitation".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to obtain "methods of use treating ras-associated diseases without limitation" as claimed.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA

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1975. Incorporation of the named diseases into the claims would obviate the rejection, see page 6, lines 20-31.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11, recites the limitations "phenoxy optionally mono or di substituted", "benzyloxy optionally mono or di substituted", and "phenyl optionally mono or di substituted", which are ambiguous and indefinite, see page 4, lines 5-9. It is unclear what the "mono or di substituted" of R_3 , R_4 , R_5 , or R_6 are. Incorporation of the scope of "optionally mono or di-substituted of phenoxy, phenyl or benzyloxy" of the compound of formula I into the claims would obviate the rejection, see page 5, lines 20-27.

Claim 19, lines 1-2, recites the limitation "ras-associated disease in mammals is phenyl modifications or proteins", which is ambiguous and indefinite. It is unclear what the ras-associated disease in mammals is. Clarification is required. . Incorporation of the named diseases into the claims would obviate the rejection, see page 6, lines 20-31.

Objection

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7. Claim 15 is objected. It appears that there are typographic errors of the disclosure "13-[3-(4-chlorophenyl)prop-2-ynyl-3-(4-methylbenzenesulfonyl)-pyrrolidine-2,5-dione" of the claim, see page 24, Example 2.

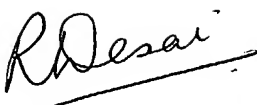
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

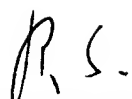
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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for

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626


Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

May 3, 2004